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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,697	04/12/2006	Carsten Olsen	10442.204-US	2080
25908 7590 12/31/2007 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER DESAI, ANAND U	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 12/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,697	<b>Applicant(s)</b> OLSEN ET AL.	
	<b>Examiner</b> Anand U. Desai, Ph.D.	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-49 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-34, and 37-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 35, 36, 38 (drawn to non-elected species), 39 (drawn to non-elected species), 40-47, 48, and 49 .

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group I, claims 30-47, drawn to a bacterial host cell comprising at least two copies of an amplification unit in its genome in the reply filed on October 15, 2007 is acknowledged. Applicant's election with traverse of the species *metE* as a conditionally essential gene in the reply filed on October 15, 2007 is acknowledged. The traversal is on the ground(s) that species are clearly linked by the inventions of cancelled claims 1-7, and that Rasmussen does not teach or suggest the technical feature of the claimed invention. This is not found persuasive because Rasmussen does disclose a method for producing a polypeptide, comprising (a) culturing a bacterial host cell comprising two or more amplified copies of an amplification unit in the chromosome, said amplification unit comprising: i) an expression cassette comprising at least one copy of a gene of interest encoding the polypeptide; and ii) at least one expressible copy of a chromosomal gene of the host cell encoding at least one enzyme involved in the removal of UDP-galactose from the bacterial cell when the cell is grown in the presence of galactose or a galactose precursor; and (b) recovering the polypeptide (see claim 1). Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 35, 36, 38 (drawn to non-elected species), 39 (drawn to non-elected species), 40-47, 48, and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups and species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on October 15, 2007.

3. Claims 30-34, 37, 38 (drawn to methionine synthesis), 39 (drawn to elected *metE* sequence) are currently under examination.

#### ***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant application. The priority date is October 31, 2003.

#### ***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on April 12, 2006 is being considered by the examiner.

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 30-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-30 of U.S. Patent No. 6,762,040 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to a host cell produced by the method comprising two or more amplified copies of an amplification unit integrated into the host cell chromosome, wherein the method comprises the steps of: (a) providing a bacterial host cell wherein a chromosomal gene encoding at least one enzyme involved in the removal or UDP-galactose is non-functional, whereby the host cell is susceptible to inhibition by UDP-galactose endogenously produced by the host cell when the host cell is cultivated in a medium comprising galactose or a galactose precursor; thereby rendering the host cell auxotrophic (b) introducing a nucleic acid construct into the host cell of step (a), the construct comprising an amplification unit, and said amplification unit comprising: i) an expression cassette comprising at least one copy of a gene of interest; and ii) an expressible copy of the chromosomal gene of step (a) or a partial non-functional copy of the chromosomal gene of step (a), wherein at least one copy of the amplification unit integrates into the host cell chromosome; (c) cultivating the host cell of step (b) in a medium comprising galactose or a galactose precursor, wherein the at least one chromosomally integrated copy of the amplification unit is duplicated or multiplied on the host

cell chromosome; and (d) selecting a host cell comprising two or more chromosomally integrated amplified copies of the amplification unit. The claims are of overlapping scope.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 30-34, and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The term "substantially" in claim 30, line 3 of step ii) is a relative term which renders the claim indefinite. The phrase "transcribed from a heterologous promoter having an activity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What amount of activity is considered to be substantially lower?

11. In claim 30, it is unclear if the amplification unit is integrated into the genome or is an autonomously replicating unit that is extrachromosomal? Suggest, in place of "...in its genome..." to clarify with ...an amplification unit that is integrated into the genome....

12. Claims dependent on rejected claim 30 fail to cure the indefiniteness and are rejected for depending on a rejected claim.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed products only by their functional properties. The court held this sort of functional definition insufficient. “In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as ‘vertebrate insulin cDNA’ or ‘mammalian insulin cDNA,’ without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its



definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.” *UC v. Lilly*, at \*24-\*25, thus the above claims lack adequate written description. The disclosure does not direct one of ordinary skill in the art to an amino acid structure that is at least 75% identical to a *metE* sequence as currently claimed.

#### ***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 30-32, 34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Glenting et al. (Applied and Environmental Microbiology, 68(10): 5051-5056 (2002)).

17. Glenting et al. disclose the construction of a *Lactococcus lactis* plasmid system for the use in gene expression in *Lactococcus lactis*. The host-plasmid selection system is based on threonine complementation. Glenting et al. constructed an auxotrophic *Lactococcus lactis* strain, which carries deletion in two genes encoding threonine biosynthetic enzymes. The plasmid pJAG5 is used for complementation and encodes homoserine dehydrogenase-homoserine kinase as selective marker. *Staphylococcus aureus* nuclease gene was cloned into the pJAG5 plasmid to generate pJAG6 (see Materials and Methods).

18. Claims 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Rasmussen (U.S. Patent 6,762,040 B2).

19. Rasmussen discloses a host cell produced by the method comprising two or more amplified copies of an amplification unit integrated into the host cell chromosome, wherein the method comprises the steps of: (a) providing a bacterial host cell wherein a chromosomal gene encoding at least one enzyme involved in the removal or UDP-galactose is non-functional, whereby the host cell is susceptible to inhibition by UDP-galactose endogenously produced by the host cell when the host cell is cultivated in a medium comprising galactose or a galactose precursor; thereby rendering the host cell auxotrophic (b) introducing a nucleic acid construct

into the host cell of step (a), the construct comprising an amplification unit, and said amplification unit comprising: i) an expression cassette comprising at least one copy of a gene of interest; and ii) an expressible copy of the chromosomal gene of step (a) or a partial non-functional copy of the chromosomal gene of step (a), wherein at least one copy of the amplification unit integrates into the host cell chromosome; (c) cultivating the host cell of step (b) in a medium comprising galactose or a galactose precursor, wherein the at least one chromosomally integrated copy of the amplification unit is duplicated or multiplied on the host cell chromosome; and (d) selecting a host cell comprising two or more chromosomally integrated amplified copies of the amplification unit. The expression vector can comprise a DNA molecule, linear or circular, that comprises a segment encoding a polypeptide of interest operably linked to additional segments that provide for its transcription. Such additional segments may include promoter (see e.g. col. 4, line 65 through col. 5, line 44). The host cell is inhibited from growth in the presence of galactose, because the gene encoding at least one enzyme involved in the removal of UDP-galactose is non-functional. The nucleic acid construct comprises an enzyme capable of preventing the inhibition of growth in the presence of galactose (see claim 19).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

*Conclusion*

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 26, 2007  
AD  
/Anand Desai/  
Patent Examiner  
Art Unit 1656